PTK61478

MICROSTIMULATORS AND MICROTRANSDUCERS FOR FUNCTIONAL NEUROMUSCULAR STIMULATION

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ABSTRACT

Work at the **Alfred E Mann Foundation** is increasingly directed towards a medium to large scale manufacturing of microstimulators. Methods are being developed for reliable and reproducible manufacturing procedures that can utilize batch-processes rather than production steps on an individual basis. Tests and testing methods are being identified along with corresponding testing fixtures and instrumentation.

During the last quarter, methods and techniques for a batch process tantalum to glass seals were successfully investigated and implemented. Even though some problems have not been solved, they have been identified and solutions are being sought.

In production, testing of subassemblies is essential for the successful final test. A testing protocol, fixture, and instrumentation have been identified for a critical manufacturing stage.

Work at **Queen's** in this quarter concentrated on two types of testing of μStims:

Mechanical tests of the strength of the glass capsule were combined with "drop tests" in which capsules instrumented with strain gauges were subjected to calibrated impacts while buried at calibrated depths in muscle tissue. These tests showed that the probability of breaking a μStim in situ in a patient is very low even with impacts that would cause significant soft tissue injury. We have also identified and begun testing of two types of very thin-walled, heat shrinkable, biocompatible polymeric tubing that successfully retain glass shards in the event that a μStim capsule is crushed during surgical handling or post-insertion trauma.

The chronic in vitro test facility was rebuilt and reprogrammed to make it compatible with the rest of our Windows PC software and to extend its measurement and record-keeping abilities to include complete μStim output characterization tests under a variety of pulse and train conditions.

During the past quarter work at the **Pritzker Institute** has focused upon winding of coils on prototype microstimulator modules, evaluating transmitter requirements for these microstimulators, and preparation of an SPIE conference presentation paper.

INTRODUCTION

We are developing a family of implantable micromodular devices for use in functional electrical stimulation (FES) for various clinical applications, including reanimation of paralyzed limbs.

These devices fall into two categories:

1. Microstimulators that generate precisely metered, highly localized electrical pulses.
2. Microtelemeters that digitize and transmit data from bioelectrical sources and transducers.

Large numbers of these devices can be implanted and controlled by a single, external coil that transmits power and command signals by inductive coupling from a highly efficient power oscillator and modulator circuit in a wearable control box. The devices generally consist of a microcoil wound on a ferrite core, a custom IC chip, and a glass cylindrical capsule (approximately 2 mm diameter by 10 mm long) which may contain glass-to-metal feed-throughs for electrodes at the ends.

This contract is concerned with the further development and in vitro testing of the microstimulator package and specialized electrodes that store energy for stimulus pulses in an electrolytic capacitor consisting of anodized tantalum, activated iridium and the intervening body fluids. It also requires the development of a transducer suitable for sensing the angle of the wrist and the development of a microtelemetry module for outward transmission of this signal.

Work at the Alfred E. Mann Foundation

Developing of a Batch Glass-Seal Process

Attempts to make the microstimulator more manufacturable were in the center of the efforts at the Alfred Mann Foundation. Pilot experiments were performed to evaluate the feasibility of a batch production of the tantalum-to-glass feed-throughs.

On the tantalum electrode side of the microstimulator, a tantalum stem, connected to the tantalum capacitor slug penetrates through the glass capsule. So far, the tantalum-to-glass seal has been made using an infrared laser beam heating up a glass bead on a rotating tantalum stem, thus hermetically fusing tantalum stem and the glass bead. The procedure was very effective, but also tedious and time consuming since each seal had to be done individually. This procedure also required a certain distance between the tantalum slug and the glass bead to prevent overheating of the slug during the sealing process. In recent discussions it was suggested by the researchers at Queen's that the neck created by the stem between the slug and the glass capsule should be eliminated to avoid excessive tissue ingrowth. Both the request from the Queen's and the high labor stress factor during laser glass-to-stem sealing led us to investigate other solutions. A batch process, utilizing high temperature, programmable electrical furnace and an associate retort with a controllable inert gas flow appeared as a possible solution.

A holding fixture was manufactured from a block of green machinable ceramic. The design took into consideration the 2-3% shrinkage during firing stage. After firing the ceramic fixture, tantalum slugs were loaded into it with stems pointing vertically up. Glass

beads were threaded onto the stems, allowing them to rest on the slugs, so minimizing the gap between the glass bead and the slug. The fixture was loaded into the furnace. Temperature was set to between 800 and 900 degrees Centigrade. High purity argon (99.999%) was fed into the retort to prevent tantalum from oxidizing or burning. The first load, consisting of 12 samples came out of the furnace after 14 hours. Ten out of twelve samples from this batch demonstrated helium leakage rates better than 1×10^{-10} atm-cc/sec. We are still investigating the best temperature profile and inert gas flow rate to minimize the glass bead deformation (or asymmetrical bead shape) and to reduce minimal but still noticeable brittleness of the stem after the exposure to high temperatures.

A similar batch procedure was attempted with the feedthrough on the iridium electrode side of the microstimulator. In this case we deal with a glass bead sealed to a platinum iridium tube. We were successful in making the original seal which again rated better than 1×10^{-10} atm-cc/sec. However, secondary sealing of the glass tube to the bead broke the original seal. Currently we are looking into possible remedies.

Testing of Microstimulator Subassemblies

Before the microstimulator is sealed into a glass capsule, electrical tests take place at several levels. One of them is after the electronic parts have been attached to the micro PC board (μPCB), the wire-bonds are in place and protected by a top-glob and the μPCB and microstim chip have been sandwiched between the ferrite half-cylinders. (The next production step is winding of the receiving coil on the ferrite core and soldering of its ends

to the μPCB.) This test verifies the proper functioning of the assembly and detects possible shorts, open connections or damaged parts.

On the μPCB, all the relevant nodes from the top side appear also on the back side. While the top side is covered by the glop-top, the back side is still exposed. This makes possible testing of all the microstimulator electronic functions such as proper response to device address, pulse width and current amplitude.

A probe card has been designed and manufactured that allows testing of microstimulator subassemblies on the described level. The card contains four probes, namely "coil hot", "coil low", "Ta electrode" ,and "Ir electrode" that can access the corresponding nodes on the μPCB.

A holding jig maintains the microstimulator subassembly in a predetermined position so that the probes make accurate contacts with the exposed pattern on the back of μPCB.

The probes on the probe-card are connected to an electronic circuit that simulates the RF input and the output capacitor and which in turn is connected to a final state logic machine and a personal computer that generate command sequences and modulate a 2 MHZ carrier signal. The carrier intensity can be adjusted with a variable attenuator which enables identifying the RF power range within which the subassembly operates reliably.

During the test, the output of the subassembly is monitored on an oscilloscope.

RESNA Manuscript Preparation

We will present the work associated with the modification of the first microstimulator chip using gold bumps this year at the 1996 RESNA conference in Salt Lake City. The accepted paper is part of the Appendix.

Work at Queen's University

Mechanical Tests

Two questions about the long-term biocompatibility of the μStim are frequently asked:

1. What happens if the glass capsule breaks in the patient?
2. Does the μStim tend to migrate through muscle after implantation?

The problem of migration has not been seen in any of the 20 chronically stimulated devices implanted in cats to date, based on stability of muscle recruitment parameters and location observed at post mortem. Nevertheless, there is a popular notion that elongated objects migrate readily through muscle. In order to compare the apparent positional stability of μStim s with other objects, a tracer study has been conducted in which glass capsules with various blunt and sharp profiles were tagged with procion yellow, a long-lived stain that is taken up immediately by and remains in muscle fibers for a long period of time. Detailed results of this study will be reported in the next QPR.

We have also examined the worst-case scenario of capsule fracture in previous studies of passive implants by injecting fragments of the glass capsule and other internal components of the μStim, which produced a somewhat thicker but localized encapsulation in the muscle. Nevertheless, fracture of the devices and release of glass shards is conceivable under some extreme conditions and would certainly be undesirable. Perhaps

the most likely scenario would be fracture of the μStim during handling by the clinician, particularly if hard surgical instruments such as clamps and forceps were used inappropriately. In this case, the obviously broken μStim would not be implanted, but the possible release of glass shards onto a sterile surgical field would pose a problem. Largely for this reason, we have obtained samples of ultra-thin walled, heat-shrinkable tubing that can be applied over the glass capsule of a completed μStim to retain any shards without adding significantly to the outside diameter of the capsule, which is sized to slide through the lumen of a 12 gauge intracath needle. Samples of medical grade polyethylene and Teflon with a final wall thickness of about 1 mil (.001" = 25 mm) have been obtained and used successfully over dummy glass capsules to capture their fragments following various crushing and bending fractures. These materials will be added to our current in vitro and in vivo biocompatibility testing program.

We have also undertaken a detailed analysis of the probability of fracturing an implanted μStim as a result of trauma. The symmetrical, elongated capsule is obviously most vulnerable to fracture in soft tissue from bending stresses applied to its long axis. Figure 1 shows the results of three-point bending applied in an Instron test machine to three different lengths of glass capsule, padded in a thin, soft silicone tube to prevent stress risers at the bearing points. As predicted for a mechanical beam, the breaking point decreases linearly with increasing capsule length. The 12 mm support length corresponds most closely to the worst-case loading of the current μStim glass capsule while the shorter lengths correspond to shorter capsules in which it appears to be feasible to place our

current components (probably with some decrease in power transmission and misalignment tolerance).

The most likely scenario in which an implanted μStim would be subjected to such bending forces would be during blunt trauma in which the muscle in which the device was located was compressed between an impacting object and an underlying bone. In collaboration with the Clinical Mechanics Group at Queen's University, we have devised a drop test in which calibrated forms of such impacts are applied to layers of artificial skin and pieces of beef. At measured depths and lateral positions within the tissue, we positioned two μStim dummy capsules equipped with pairs of strain gauges along their longitudinal axis. The oscilloscope photo in Figure 2 shows a typical recording of the impact detected a load cell under the beef (bottom trace) and the strains produced in a μStim capsule directly under the center of impact (center trace) and offset by 1.4 cm laterally (top trace). The offset capsule lies parallel to the central capsule but is displaced 1 cm laterally and 1 cm longitudinally to capture stresses that might arise in the lateral propagation of the impact pressure wave through the muscle.

The main finding is that bending strain occurs only during the initial pressure wave in the muscle associated with the initial impact of the bullet. The highest recorded strain was about 25% of the 2 kg breaking point in the Instron test, with most values well below 10%. Strains were considerably lower when the thicknesses of muscle padding were reversed (2 cm above, 1 cm below) because bending force results from asymmetrical gradients in the pressure wave. These are maximal when the impact and support surfaces have different shapes from each other and when the straight capsule is closest to the more

curved surface. The impacts all produced gross deformation and dissection of the muscle fascicles around the glass capsule but no capsules were broken. We were unable to complete the full series of planned impacts because of repeated rupturing of the fine wire leads attached to the strain gauges on the capsules; additional testing and a detailed report are still in progress. However, the results clearly show that fracture of a μStim in vivo is highly unlikely and would occur only with severe trauma in which the damage from the trauma would far exceed that caused by the disrupted μStim itself.

Electrical Output Tests

Because of the capacitor electrode, μStim s function normally only with their electrodes immersed in saline. Their output stimulation pulses cannot be measured by direct probing of the electrodes themselves, but must be sensed indirectly by detecting electrical fields produced by the current pulses in the volume-conductive saline. The Appendix on "Chronic Microstimulator Tester" shows the design and sample outputs of a new test system that uses the same hardware platform used in the Clinical Bedside Controller (based on a Motorola 68HC11 microprocessor and a field-programmable gate array) and compatible Windows-based software for graphic user interface and database maintenance. The PC-based test system will also control an automatic temperature-cycling oven.

μStim serial #10004 represents one of the old-style packages with an IC chip that produces the nominal output current amplitudes. The measured amplitudes show a threshold value of 4 mA, which is actually associated with the noise floor in the pulse detection software of the testing station, and a saturation value of around 20 mA, which is

related to the compliance voltage limit of about 8.5V in the relatively high resistance test chamber. μStim serial #10085 is a new-style package with an IC chip that was designed to produce twice the nominal stimulus pulse and recharge currents. The measured amplitudes show the expected decrease in threshold to the 2 mA requested current level and saturation at around 10 mA requested current (actually 4 mA and 20 mA, respectively). Actual calibrations of output current have been obtained previously using a divided bath with a bridging resistor, similar to the classic sucrose gap technique used to measure action currents from squid giant axons. For both of these devices, the tests of output pulse widths and the decreases of output amplitude with stimulus frequency above the nominal 50 pps rating are well within specified tolerances.

As soon as a sufficient supply of new μStim s have completed package hermeticity and glass stress analysis, we will start long-term soaking of 8 devices at a time with elevated temperature cycling and continuous stimulation and periodic testing as specified in the Appendix.

Work at the Pritzker Institute

Prototype Microstimulators

Using measured coil parameters, and design tables which we have developed over the past year, we designed a winding configuration for the 2MHz microstimulators. The microstimulators differ from the earlier versions in that the core is of the split design, with the integrated circuit sandwiched between the core halves.

In our models and tests, we determined that core length was of the utmost importance in maximizing the coefficient of coupling between the microimplant and the transmitter coil. Similarly, coil length, along the core, should be minimized. This allows the maximum number of flux lines to cut through the coil windings. To maximize the peak current sourcing capability of the coil, the capacitance should be maximized. Maximum capacitance is obtained when the coil is fabricated from two full winding layers. This is due to the nature of the coil capacitance.

For a self resonant coil, the capacitance is formed by the proximity of one layer to the next. Although often called turn-to-turn capacitance, this term is incorrect. The capacitance resulting from one turn physically next to the adjoining turn is too small to be of any practical significance. Since each turn is in series with the previous turn, the total turn-to-turn capacitance decreases and the number of turns is increased. Consequently for a multiturn, multilayer coil, the turn-to-turn capacitance is insignificant. However, the presence of one layer next to the underlying layer forms a significant capacitance. For two layers, it is possible to adjust the ratio between the capacitance and the inductance by changing the turns-per-layer. Since the layer-to-layer capacitance depends primarily upon

the geometry of the layers, and the inductance depends upon the square of the total turns, the inductance can be varied, while keeping the capacitance fixed, by changing the wire size and retaining the length of the layers. Actual coil design is somewhat more complicated since changing the wire size also changes the quality factor of the coil. For more than two layers, the capacitance decreases roughly as 1/number of layers. Therefore, for maximum capacitance, one should design a coil with the minimum number of layers, preferably two. For the microstimulator, we have determined that the best compromise coil design is comprised of two layers of #50 wire, with 94 turns per layer.

The coils are wound on our Adams Maxwell coil winder, equipped with an electronic traverse. The coils are wound in true layered form. That is, each layer is a true helix. This provides the greatest consistency from one coil to the next. Before the wire is broken, a low-viscosity adhesive is used to fix the windings in place on the core. Using a micro-tipped soldering iron, the wires are then soldered to the rear of the micro-printed-wiring board.

Yield of the microstimulators after winding is approximately 30%. The reason for this poor yield is not yet known. The integrated circuits have been pretested. In some of the defective stimulators, measurements show that the external diode and resistor are not properly connected. In others the precise cause is unknown. Presently, test fixtures are under development, at the Mann Foundation, to permit testing of the electronic module at all assembly levels.

Transmitter Evaluation

We have been evaluating the requirements of the transmitter to operate these new microstimulators from two perspectives. First, the modulation requirements have been accessed. Second, the field strength requirements are being examined.

Using the external resistor/diode combination, the modulation requirements can be significantly relaxed. In the earlier versions of the 2MHz microstimulator, a defect related to the input diode required that the transmitter modulation be large, approximately 20% to 30%, and near-square in shape. Using the external resistor/diode combination now permits transmitter modulation to be as low as 5% and to be of triangular shape. In light of these new requirements, we are examining the power supply needs of the transmitter.

Field strength requirements are being examined in light of applications proposed by Queen's University. We have obtained a human shoulder model from Queen's and we are proposing transmitter coil and circuit configurations which could be used with microstimulators implanted into a human shoulder. The combined field strength and modulation requirements need to be used to access the power supply capacity needed for reliable transmitter operation.

SPIE Manuscript Preparation

We have prepared a conference paper entitled "Microtelemetry Techniques for Implantable Smart Sensors". The submitted manuscript is attached to this report.

APPENDIX 1

CUSTOM SILICON CHIP TECHNOLOGY FOR IMPLANTABLE FES MICROSTIMULATORS

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ABSTRACT

A microminiature multichannel implantable stimulator is being developed for the use in therapeutic and functional electrical stimulation (FES) . The stimulation system uses multiple distributed stimulation modules instead of a single unit with multiple electrode leads. Up to 256 implanted modules can be individually programmed for current amplitude and pulse width for each stimulating pulse from a single external transmitter/controller. Initially, the micro-stimulators were designed as one chip devices with one receiving coil and one electrode at each end of a hermetic, biocompatible glass cylinder. However, design and chip manufacturing errors compelled additional components, a diode and a resistor, to be added as off-the-chip parts. Also, the micro-stimulator assembly procedure changed which necessitated transposition of bonding pads on the chip using a process known as gold-bumping.

BACKGROUND

Research by Guyton and Hambrecht (1) demonstrated the biocompatibility of sintered and anodized tantalum as well as the fact that mammalian extracellular liquid can serve as the liquid electrode of a tantalum capacitor. Robblee et al (2) described the ability of activated iridium to pass high current densities without electrochemical side effects. Heetderks (3) in a theoretical study showed the feasibility of an inductively powered implant with a very small receiving coil. As a consequence, the National Institutes of Health initiated a contract that has resulted in development of extremely small implantable and addressable stimulators.

APPROACH

A development of a micro-stimulator with a minimal number of components was proposed: an integrated circuit, a self resonant receiving coil, a protective glass capsule and two stimulating electrodes. One electrode is made of activated iridium, the other is a slug of anodized sintered tantalum. The latter constitutes a wet tantalum capacitor and serves both as a power storage and a charge balance capacitor. The powering and stimulation parameters are supplied by an external, high efficiency class-E transmitter. An amplitude modulated 2 MHz carrier powers and transfers stimulation data to the micro-stimulator and provides the basic clock for the digital part of the micro-stimulator circuitry.

Since the microstimulators are addressable they represent another approach to multichannel stimulation in which each stimulation channel is one stimulator implanted directly at the stimulation site (4,5).

METHODS

An electronic circuit has been designed using a minimal number of components needed to make a implantable stimulator. A single chip circuit was developed that had only four connections: two for the receiving coil, two for the electrodes. The electronic block diagram is shown in Fig.1. The receiving coil continuously charges the tantalum capacitor/electrode through a rectifying diode. The charging current with a sub-threshold amplitude passes through the tissue between the electrodes. At a given command sent from the powering transmitter the charged tantalum capacitor is shorted and releases a stimulation pulse going through the tissue in the opposite direction as the charging current. A number of such commands, sent at a certain rate, generates a stimulation train of pulses.

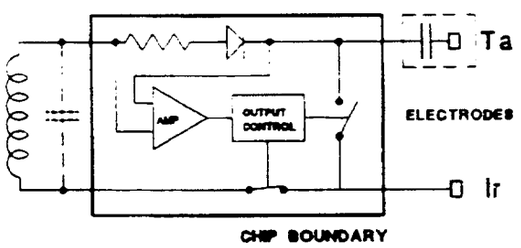

Fig. 1

The rectified RF signal also passes through a series resistor. Any amplitude modulation on the RF signal is observed on this resistor as a voltage variation. By amplifying and cleaning the signal, the information hidden in the amplitude modulation can be extracted.

Typically, the information contains idle pulses,

device address (0-255), pulse-width (3.5 μs-257.5 μs in 256 equal steps), current amplitude (0.2 mA-60mA in 32 steps) and capacitor recharge current (10 μA and 100 μA). The maximal stimulation voltage is 7.5 V and the maximal pulse rate is 637 Hz per unit.

Theoretically, 256 individual addresses can be accommodated with the number of bits reserved for addresses. In the chip production, seventeen distinctive chips were designed that differ only in their "address number". Stimulator "address" identifies the stimulation channel.

A 3 micron P-well double poly CMOS technology was selected for the chip development. This technology makes possible combination of analog and digital circuits in the same process on the same chip.

RESULTS

When trying to manufacture a micro-stimulator according to the design, we came across several difficulties. First of all, the silicon chip did not perform according to the design. The on-the-chip rectifying diode had to be bypassed by an external diode. This enabled powering of the device, however the retrieval of stimulation information became less reliable since the series resistor was bypassed with the external diode as well. In spite of that we were able to assemble several tens of microstimulators and test them in vitro and in experimental animals to verify their biocompatibility and functionality. Fig. 2 shows a schematic assembly drawing of such a micro-stimulator. A micro-stimulator is 16 mm long and 2 mm in diameter.

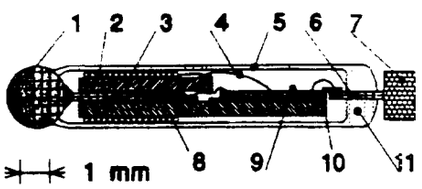

Fig.2 : 1-iridium ball; 2-Coil; 3-Ferrite; 4-Bond wire; 5-Glass tubing; 6-Feed-through; 7-Tantalum electrode; 8-Extension stem; 9-Custom chip and external diode; 10-Metal shim; 11-Glass bead.

To improve the micro-stimulator's reliability, an external resistor was added in series with the external diode which required cutting of the diode connection on the chip itself. A trimming laser was used for this purpose. Because the external diode and resistor could accept only the first bond (ball bond), an intermediate land was created that could accept the second bond, (wedge bond), and thus enable the series connection of the diode and the resistor (Fig.3). Even though the scheme

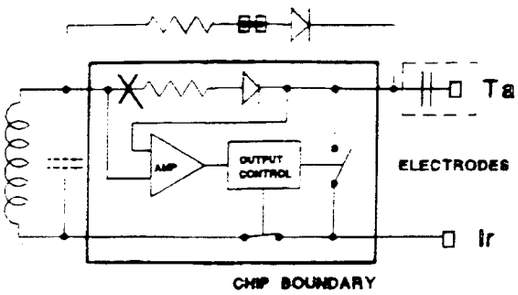

Fig.3

worked very well on a bench, due to inaccurate aim and water vapor ingress into the active silicon through the broken surface chip protection layer, these microstimulators failed to work a few weeks after encapsulation. As it can be seen, the initial idea of having only two components inside the glass capsule is severely compromised. Therefore it was decided to change completely the assembly procedure, fix the errors on the chip and add components which would make the assembly easier and the device more manufacturable.

The new chips performed even worse than the first ones, so we returned to the first chip while the problems with the second chip were being identified. We intended to again use the approach with the diode trace cutting and an external diode and resistor configuration. This time, the cut in the chip protective layer would be sealed and protected by a layer of silicon nitride.

The new assembly procedure required all bonding pads to be on one side of the chip and have a certain sequence to make short bonds to the underlying micro PC Board. For that reason the old bonding pads had to be repositioned using a process called gold-bumping.

The gold-bump process can only be done on an uncut wafer and requires several operations, described below. The processed wafer is plasma cleaned and a 10,000 Å thick layer of low temperature silicon nitride is deposited over the wafer. Photo-resist is spun over the nitride and the old bond pads are exposed. The nitride is etched off at the pads and the rest of the

photo-resist is washed off. A 2,000 Å thick layer of titanium-tungsten is sputtered on the wafer. It serves as a barrier between aluminum and gold and also promotes gold adhesion. It is followed by a 1,000 Å seed layer of gold. Again the photo-resist is spun on the wafer, its thickness defines the thickness of the future gold traces. The photo-resist is exposed to UV light through a mask showing the traces and subsequently developed. The wafer is plasma etched (few minutes in oxygen or argon) for one more time to remove the remnants of photo-resist. This leaves the seed layer of gold exposed. The gold-bumps are then electroplated on the seed layer to the desired thickness. Then the unexposed photo-resist is removed. The wafer is dipped into an etch solution which removes the layer of titanium- tungsten. Cleaning and rinsing is required at the end of the process.

This time the diode trace was cut manually, using an ultrasonic trace cutter. It took 50 cutting probe tips and two weeks to cut diode traces on more than 1,200 chips on the wafer.

A wafer with gold-bump chips delivered from a vendor was 100% electrically tested. There were 1,003 good chips and 136 bad chips on the wafer, which represents a 88% yield.

Transposition of bonding pads enabled us to use the previously manufactured μPC Board as the μstim chip substrate. To accommodate the additional resistor the conducive areas on the μPC Board were reassigned. This modification required one long bond wire going from the chip pad to a distant conductive area on the μPC board. To stabilize this and other bond wires, a glob top epoxy has to be applied over the exposed chip and bond wire area.

DISCUSSION

Custom made silicon chips with combined analog-digital circuits are expensive to design and manufacture. Very often the first or even the second attempt to make a fully working chip results in a failure. In our case we were dealing with a chip that had a defective diode on board, which made the chip useless. Luckily, the position of the diode in the circuit and physically on the chip was such that it could be effectively removed from the chip and replaced by an external diode. Moreover, the resistor, essential for the data demodulation, was also conveniently placed and could be replaced by an external device. Having two additional devices in a small package required redesign of the package which in turn demanded repositioning of the bonding pads using a relatively inexpensive gold-bumping process.

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APPENDIX 2

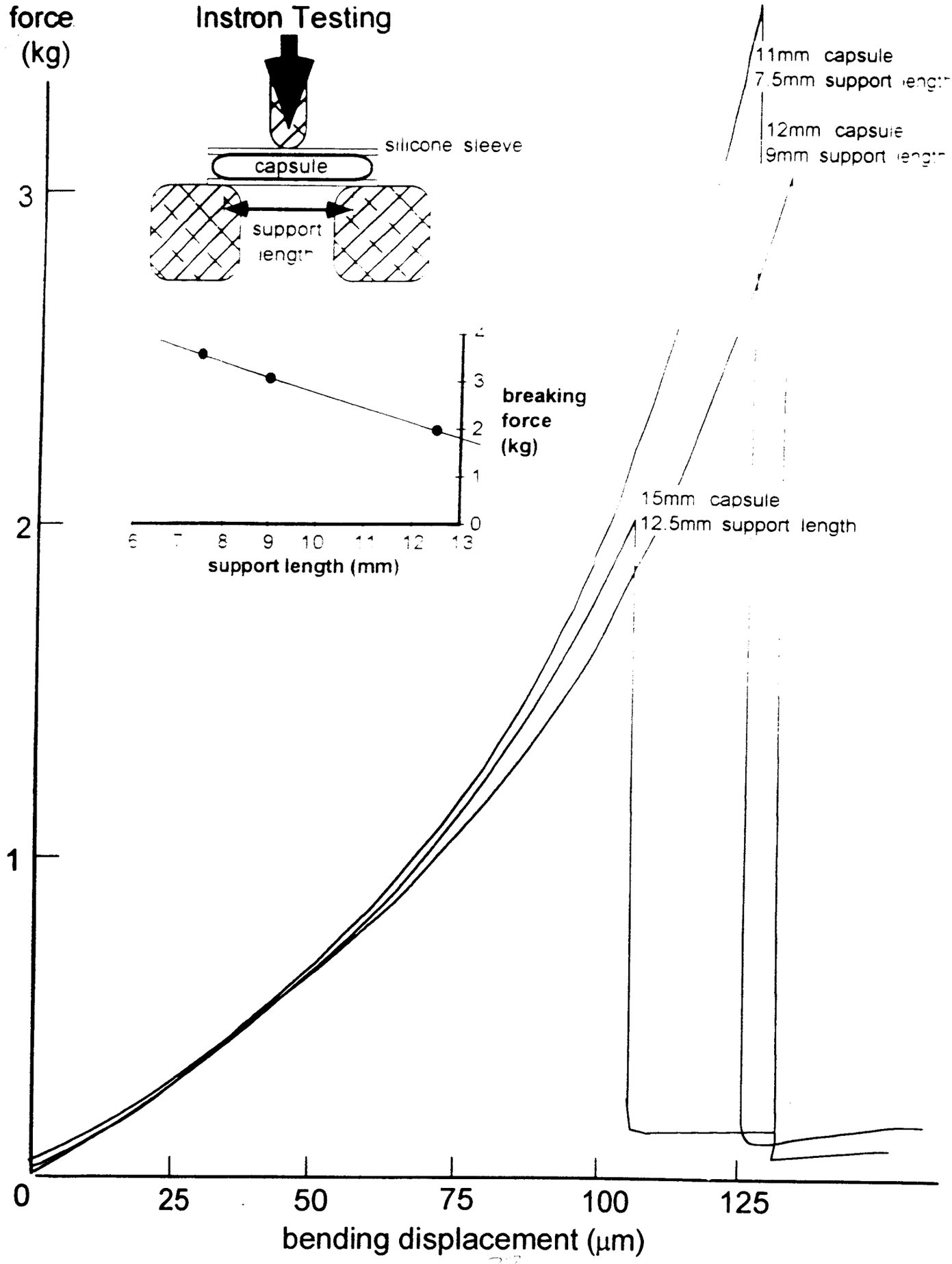
force (kg)
Instron Testing
silicone sleeve
capsule
support length
11mm capsule
7.5mm support length
12mm capsule
9mm support length
15mm capsule
12.5mm support length
breaking force (kg)
support length (mm)
bending displacement (μm)
0
25
50
75
100
125
1
2
3

FIGURE 1

Test 1, Trial 2: 50 mm diam. bullet
0.5 kg mass
dropped from 0.36 m

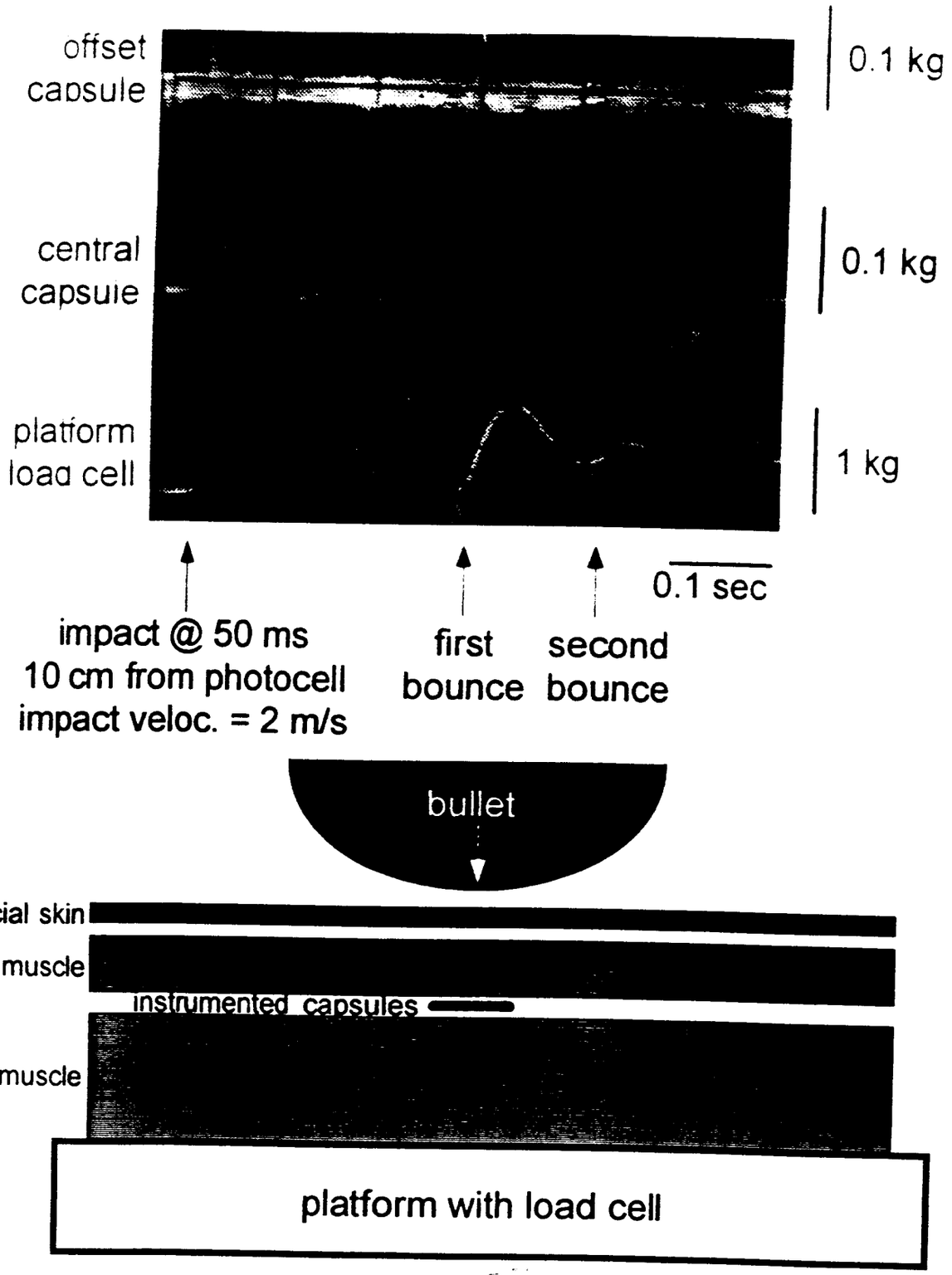

FIGURE 2

Chronic Microstimulator Tester

Bio-Medical Engineering Unit
Queen's University
December [illegible]

About This Document

This document describes the test system to be used in the characterization and chronic testing of microstimulators.

System Hardware

Temperature Control

Chronic testing takes place in a heated oven. The temperature will cycle from low (35C) to high (85C) once every 12 hours with three hours being spent at the low temperature and roughly 9 hours at the high temperature (not including heat-up and cool-down times). The heat-up and cool-down transitions will be as fast as the oven will allow.

Control of the oven will be from the Windows software. One pin on the PC parallel port will be used to drive a relay that turns the oven heater on and off.

Testing Procedures and Protocol

The procedures and protocol for testing microstimulators involves several steps:

Installation

The microstimulator is placed in a test-well. During a single test run, a microstimulator should remain in the same well. Each time a microstimulator is removed from its initial position, a microstimulator test is considered to be ended and the associated test record is closed. If the same microstimulator is replaced in the test apparatus, a new test record is opened.

Characterization Testing

A characterization test is performed to evaluate the full range of operation of a microstimulator at a specific point in time. This evaluation involves:

1. Obtaining the microstimulator address for any specified well.
2. Test each possible pulse amplitude at maximum pulse width. Cycle through all 32 possible pulse amplitude values measuring the output voltage for each pulse amplitude. The two chip dependent bits are set for a square wave pulse and high recharge current.

3 Test a series of pulse widths at a fixed amplitude of 10 mA. Measure the actual pulse width for each programmed pulse width.

4 Measure the maximum sustainable frequency. With a 10mA amplitude and maximum pulse width, apply 100 pulses at different intervals (40ms, 20ms and 10ms) and measure the relative amplitude of the last pulse in the train relative to the first pulse.

Characterization tests can be run both as part of chronic testing and on demand.

Chronic Testing

Chronic testing takes place over a period of several hours to several days. Microstimulators are placed in a particular test well and a test signal of 10mA and maximum pulse width at 50 pulses per second is applied continuously. Every hour, the test signal is stopped. A test pulse is applied and the resulting signal is measured (amplitude and pulse width) and recorded. After all 8 microstimulators are tested, the continuous test signal is reapplied.

The chronic testing cycle has a duration of 12 hours and is tied to the cycling of the temperature in the testing oven.

A chronic test measurement is made once per hour for each installed microstimulator. One characterization test is made per 12-hour cycle just before the temperature ramps up from low to high.

Spot Testing

Spot testing can be performed at any time that chronic or characterization testing is not being performed and involves manual selection of all parameters that can be sent to a particular microstimulator in a particular well. These parameters include pulse amplitude and duration and pulse frequency (pulse shape and recharge current?).

Data Organization

The data for the Chronic Tester consists of configurational information and data resulting from microstimulator testing. Testing data is stored in a flat ASCII file format consisting of header information and tab-delimited data arranged for easy importing into most standard spreadsheet applications. Configurational data, including information on each microstimulator being tested, dates and times of testing, etc., is stored in a central application database which includes pointers to the various ASCII data files.

The ASCII chronic and characterization data files are stored in the DATA subdirectory of the main application directory. Each microstimulator that is tested has two files with the same file name but different extensions created for it. The file name is created by the chronic tester based on the microstimulator serial number. The file extensions are CDA for chronic test data and CDB for characterization test data.

Chronic Data File Format

Chronic data files have the extension CHR. Each chronic data file consists of a header and a block of data.

The chronic data file header consists of the following information:

- **Creation date and time**: The same date and time that is stored in the main testing database.
- **Microstimulator serial number**.
- **Microstimulator address**.

The data block follows the header and consists of multiple records, one per line, each record containing the data for one chronic measurement for the specified microstimulator. Each record consists of two items separated by TABs:

- **Time stamp**: Date and time when the measurement was made.
- **Amplitude**: Strength of the measured signal in milliamps after the appropriate signal has been applied to the microstimulator (see the section on chronic testing above).

Characterization Data File Format

Characterization data files have the extension CHA. Each characterization data file consists of a header and one block of data per characterization test. Blocks are numbered sequentially from 1 as they are added to the file.

The characterization data file header is identical to the header for the chronic data file.

Each time characterization data is measured, a data block is appended to the file. The block name has the form [Data_xxx] where 'xxx' is numbered consecutively to identify the block. Following each header is a number of rows each of form:

ITEM= VALUE

The following ITEM/VALUE pairs are included for each data block:

- **Time stamp**: ITEM = "TimeStamp". VALUE = general date and time (e.g. "12/13/95 11:55:16 AM")
- **Pulse Amplitude Test Data**: ITEM = "Amplitude". VALUE = a string of 32 values each two hexadecimal digits representing a value from 0 to 255. Values are separated by commas. Each amplitude value, A, represents a measured voltage, V, where

  V = A * (5 / 256) Volts
- **Pulse Width Test Data**: ITEM = "Width". VALUE = a string of 32 values, each two hexadecimal digits representing a value from 0 to 255. Values are separated by commas. Each width value, W, represents a measured interval, I, where

  I = (0.5 * W) mS
- **Maximum Sustainable Frequency Test Data**: Two rows of information representing the measured pulse amplitude at the beginning and end of the 100 pulse sequence. The two rows have ITEM = "FrequencyInitialAmplitude" and "FrequencyFinalAmplitude" respectively. For each row, VALUE = a string of 3 values, each two hexadecimal digits representing a value from 0 to 255. Values are separated by commas. Each amplitude value, A, represents a measured voltage, V, as given for the pulse amplitude test data above

An example characterization data block is given below:

```
[Data_005]
TimeStamp=17/01/96 16:09:00
Amplitude=00,00, ... ,00,00,17,1D,23,29,2E,33,36,3A,3E,3E,3F
Width=0000,000B,000D,0013,001D,0032,0162,0002,0199,0218
FrequencyInitialAmplitude=3F,3D,40,3F
FrequencyFinalAmplitude=12,1B,29,3A
```

System Software

The Chronic Tester software is written as a Microsoft Windows application.

Microstimulator Installation

To install a microstimulator for testing, the following data is recorded in the system database:

- Serial number (provided by manufacturer).
- Test well (1 - 8).
- Address (0 - 255). This can be measured by the test apparatus.
- Install Date. Added automatically.
- Characterization data file name. Created automatically from the microstimulator serial number.
- Chronic data file name. Created automatically from the microstimulator serial number.

- Notes Free form text

Test Initiation

Test Status

The Chronic Test software displays the current test status of all installed microstimulators at all times This includes

- an identification of which microstimulator is in each test well
- the number of chronic test measurements made for each microstimulator
- a plot of the chronic measurement results for one or more microstimulators

Communication Protocol

The command set used for communication between the bench-test hardware and the high level Windows software is described in this section.

Command	Description
(A	Measure pulse amplitude in specified test well
(C	Check for active bench-tester.
(D	Download test channel parameters.
(F	Find address.
(G	Get one set of chronic data measurements.
(M	Measure maximum sustainable frequency in specified test well.
(S	Stop chronic testing.
(T	Start chronic testing.
(V	Verify address.
(W	Measure pulse width in specified test well.

(A Measure pulse amplitude in specified test well. The full syntax for this command is:

(Accvvss)

where "cc" indicates the test well, "vv" is the value of the pulse amplitude to apply to that address (00-1F), and "ss" is the checksum for the string "ccvv"

If there is an error in the command "E" is returned. Otherwise, the returned information has the form:

(Avvss)

where "vv" is the measured pulse amplitude (00-FF), and "ss" is the checksum for the string "vv"

(C Check for active testing unit. If the bench-tester is working, an "A" is returned. If anything else or nothing is returned then the bench-tester is non-functional and should be restarted, or there is a problem with the serial communications.

(D...) Download test-channel parameters. The full syntax for this command is

(Dccaawwmmss)

where

cc is the channel number: 01, 02, ... 08

aa is the microstimulator address: 00 ... FF

ww is the pulse width: 00 ... FF

mm is the mode control: 00 ... FF

ss is the check sum: 00 ... FF

The checksum is calculated by adding the ASCII values of ccaawwmm and reducing to a hex representation for the reduced byte. Example BASIC code to perform the checksum calculation is given in Appendix A.

An error occurs if the command is invalid (e.g. bad checksum).

(F Find address. The full syntax for this command is:

(Fccss)

where

cc is the channel number: 01, 02, ..., 08

ss is the check sum: 00 ... FF

The bench-tester tries every microstimulator address from &H00 to &HFF and returns a string indicating the address found the specified test well.

If there is an error in the command "E" is returned. Otherwise, the return string format is:

(Faass)

where "aa" is the ASCII encoded hex values ("00" to "FF") for the addresses found for channels 1 to 8 respectively. If an address is not found for a given test well then "XX" is returned. "ss" is the checksum for the returned string "aa...hh" calculated as in Appendix A.

(M Measure maximum sustainable frequency in specified test well. The full syntax for this command is:

(Mccppss)

where

cc is the channel number: 01, 02, ..., 08

pp is the period in units of 5ms (e.g. 01=5ms, 02=10ms, etc.)

ss is the check sum: 00 .. FF

If there is an error in the command "E" is returned. Otherwise, the returned information has the form:

(Mvvwwss)

where "vv" is the measured pulse amplitude at the start of the cycling, "ww" is the measured pulse amplitude at the end of the cycling, and "ss" is the checksum for the string "vv".

(T Starts testing. The bench-tester begins cycling through the channel data, sending it in sequence to the 8 channels. If there is an error in the command "E" is returned. Otherwise, "A" is returned.

(S Stops testing. The bench tester stops its testing cycle. An "A" is returned if successful. An "E" is returned if an error occurs (e.g. the bench-tester is not running).

(G Get one set of chronic data measurements.

If there is an error in the command "E" is returned. Otherwise, if the bench-tester is running, it is temporarily stopped and each channel has both pulse width and pulse amplitude measured. These are returned in a single string of format:

(Uaaaaaabbbbbb...hhhhhhss)

where aaaaaa (bbbbbb, ..., hhhhhh, etc.) are 6 ASCII bytes for channel 1 (2, ..., 8) encoding three bytes of information: Pulse width *W* (first 4 characters = 2 bytes) and pulse amplitude *A* (last 2 characters = 1 byte).

The pulse width value, *W*, has the range: &H0000 <= *W* <= &HFFFF. If *W* >= &H8000 then it should transformed according to *W* = &HFFFF-*W*. The actual time duration represented by *W* is given by *W* * (500*10E-9) Seconds.

The pulse amplitude value, ***A***, has the absolute range &H00 <= ***A*** <= &HFF. The valid range, however, is &H00 <= ***A*** <= &H75. Values outside this range are suspicious. The actual voltage represented by ***A*** is given by ***A*** * (5 / 256) Volts.

If the bench-tester is not running, an error occurs and "E" is returned.

(V Verify the specified address for the specified test well. The full syntax for this command is

(Vccaass)

where

cc is the channel number: 01, 02, ... 08

aa is the address to test: 00 ... FF

ss is the check sum: 00 ... FF

If there is an error in the command "**E**" is returned. Otherwise "**A**" is returned indicating that a microstimulator responded as expected, or "**X**" is returned if no microstimulator responded.

(W Measure pulse width in specified test well. The full syntax for this command is

(Wccvvss)

where "**cc**" indicates the test well, "**vv**" is the value of the pulse width to apply to that address (00-FF), and "**ss**" is the checksum for the string "**ccvv**".

If there is an error in the command "**E**" is returned. Otherwise, the returned information has the form:

(Wvvss)

where "**vv**" is the measured pulse amplitude, and "**ss**" is the checksum for the string "**vv**".

Appendix A : Example Basic code for checksum calculation.

Given an ASCII string, the resulting checksum is calculated by adding up the integer ASCII values for each digit and reducing to a single byte value (modulo 256). Visual Basic code for calculating the checksum is given below:

```
Function nCheckSum(sCheckString as string) As Integer

    Dim N As Integer
    Dim sTmp As String
    Dim nSum As Integer

    nSum = 0
    For N = 1 To Len(sCheckString)
        sTmp = Mid$(sCheckString, N, 1)
        nSum = nSum + CInt(Asc(sTmp))
    Next N

    nCheckSum = nSum Mod 256

End Function
```

Microstimulator Circuit Tester
Characterization Test Report

Serial Number: 10014
Address: 4
Time-Stamp: 17:11.96 10/15/
Data File: 10014.CHA

Amplitude Tests

Test,	Amplitude Sent, mA,	Amplitude Measured V
1,	0.00,	0.00
2,	0.20,	0.00
3,	0.40,	0.00
4,	0.60,	0.00
5,	0.80,	0.00
6,	1.00,	0.00
7,	1.20,	0.00
8,	1.40,	0.00
9,	1.60,	0.00
10,	1.80,	0.00
11,	2.00,	0.00
12,	2.20,	0.00
13,	2.40,	0.00
14,	2.60,	0.00
15,	2.80,	0.00
16,	3.00,	0.00
17,	0.00,	0.00
18,	2.00,	0.00
19,	4.00,	0.00
20,	6.00,	0.45
21,	8.00,	0.61
22,	10.00,	0.78
23,	12.00,	0.94
24,	14.00,	1.09
25,	16.00,	1.21
26,	18.00,	1.37
27,	20.00,	1.46
28,	22.00,	1.54
29,	24.00,	1.60
30,	26.00,	1.62
31,	28.00,	1.60
32,	30.00,	1.62

Pulse Width Tests

Test,	Pulse Width Sent, (uS),	Signal Measured (uS)
1,	3.0,	0.0
2,	4.0,	6.0
3,	5.0,	7.0
4,	8.0,	10.5
5,	13.0,	15.5
6,	23.0,	25.0
7,	53.0,	55.0
8,	103.0,	105.0
9,	203.0,	205.5
10,	258.0,	260.5

Maximum Sustainable Frequency Tests

Test,	Interval, (mS),	Frequency, (Hz),	Initial Signal, (V),	Final Signal, (V),	Signal Ratio
1,	10,	100.0,	1.64,	0.84,	0.51
2,	20,	50.0,	1.64,	1.27,	0.77
3,	40,	25.0,	1.60,	1.58,	0.99

Microstimulator Chronic Tester

Characterization Test Report

Serial Number: [illegible]
Address: [illegible]
Time-Start: [illegible]
Data File: [illegible]

Amplitude Tests

Test,	Amplitude Sent, (V),	Amplitude Measured (V),
1,	[illegible],	0.01
2,	[illegible],	0.01
3,	[illegible],	0.01
4,	[illegible],	0.00
5,	[illegible],	0.00
6,	[illegible],	0.00
7,	[illegible],	0.00
8,	[illegible],	0.00
9,	[illegible],	0.00
10,	[illegible],	0.00
11,	[illegible],	0.31
12,	[illegible],	0.37
13,	[illegible],	0.43
14,	[illegible],	0.47
15,	[illegible],	0.47
16,	[illegible],	0.53
17,	[illegible],	0.00
18,	[illegible],	0.57
19,	[illegible],	0.72
20,	[illegible],	1.02
21,	[illegible],	1.09
22,	[illegible],	1.11
23,	[illegible],	1.15
24,	[illegible],	1.13
25,	[illegible],	1.17
26,	[illegible],	1.19
27,	[illegible],	1.19
28,	[illegible],	1.19
29,	[illegible],	1.19
30,	[illegible],	1.21
31,	[illegible],	1.19
32,	[illegible],	1.21,

Pulse Width Tests

Test,	Pulse Width Sent, (uS),	Signal Measured (uS)
1,	3.0,	0.0
2,	4.0,	6.5
3,	5.0,	7.5
4,	8.0,	10.0
5,	13.0,	15.5
6,	23.0,	25.5
7,	53.0,	55.5
8,	103.0,	105.5
9,	203.0,	206.0
10,	258.0,	260.5

Maximum Sustainable Frequency Tests

Test,	Interval, (mS),	Frequency, (Hz),	Initial Signal, (V),	Final Signal, (V),	Signal Ratio
1,	10,	100.0,	1.19,	0.73,	0.61
2,	20,	50.0,	1.21,	1.13,	0.94
3,	40,	25.0,	1.23,	1.19,	0.97

APPENDIX 3

Microtelemetry Techniques for Implantable Smart Sensors

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ABSTRACT

The advent of the emerging field of smart sensors suggests new applications for implantable microelectronic devices in neural prostheses. Optimal use of miniature and subminiature (thin-film) electronic sensors in implanted systems will depend upon the nature of the power and communication link to the sensor. Microtelemetry technology is under current development to meet this need. Microtelemetry techniques can be used to provide operating power and bi-directional communication for a microimplant through a common, wireless, magnetic link. Owing to the extremely unfavorable geometry, i.e. the size of the implant relative to the size of the extracorporeal transmitter, the design of such links is highly parametric. Magnetic circuit parameters must be closely matched to the implant's integrated-circuit power usage. In addition, the bandwidth of the communication channel must be adequate to meet the data collection requirements. This paper describes on-going R&D work for the design and fabrication of smart sensors based upon microtelemetry technology. Presently, sensor designs for two applications are in progress - EMG and joint angle position.

2. SIGNIFICANCE OF IMPLANTABLE MEDICAL SENSORS

During the past decade, implanted medical electronic sensors and stimulators have been described and proposed for systems designed to compensate for numerous neurological disorders. Yet few, if any, of these devices have been successfully integrated into complete commercially viable clinical systems. Miniaturization, and minimal invasiveness are often requisite for system function. A major obstacle in miniature implant development remains the lack of established methodologies to provide stable electrical and mechanical interconnections to exiting lead wires. Using existing technology, lead wires are essential to providing operating power to and communication with implants. Lead wires, connecting miniature electronic implants to either larger implanted electronic packages or extracorporeal control systems, suffer from failures due to breakage, corrosion, percutaneous infection, and marsupialization.

Microtelemetry technology has been demonstrated, @ 125kHz and 400kHz, for miniature implantable electronic devices (passive transponders) commercially available for livestock identification. These transponders use micro-assembly techniques to connect a miniature solenoidal coil with an integrated circuit within a sealed glass capsule. Power to, and telemetry from (providing a unique identification number) the transponder are accomplished using magnetic coupling to the miniature coil. Based upon these devices, the Neuroprosthesis Program of the National Insititutes of Health (NINDS) is funding the development of micro-implants - untethered micro-stimulators and micro-transducers small enough to be injected into living beings through hypodermic needles.

2.2 Clinical Significance

Chronic implantation in the human body of devices such as chemical sensors, mechanical transducers, ECG and EMG recorders, and neural-muscular stimulators, has long been the goal of the users and designers of medical electronic monitoring and control systems

The size reduction of electronic systems made possible by the advancement of thin-film technology during the past ten years has increased the demand for implantable electronic systems which will answer medical needs much as has the cardiac pacemaker. Ion-sensitive FETs (ISFET) have been fabricated [1-5] and proposed for possible chronic in-vivo monitoring. Pressure transducers [6-7] have been proposed for a number of applications, e.g., Cranial pressure monitoring [8], or arterial pressure measurement [9]. Chronic neural recording has been proposed for treatment of epilepsy [10] and for the control of neural prosthetic devices [11-13].

In this latter field of functional electrical stimulation, FES, the need for totally implantable neural prostheses has been proposed in both the upper [14] and the lower [15] extremities. Most viable approaches require the use of multiple stimulation channels, as well as sensor inputs. Not limited to peripheral neural prostheses, FES is being aggressively studied for central nervous system (CNS) devices as well. These devices include CNS auditory and visual prostheses for which multi-channel stimulation of the cortex will be required. A review of FES applications [16] lists much of the present work.

We anticipate that in the next decade sensors will see an increasing use in laboratory and clinical medicine. Many examples of this proliferation are being seriously discussed in the medical devices industry. In some cases, the need may be driven by the desire to reduce health-care delivery costs. For example, it has been suggested that patients who are in long-term care institutions may be implanted with sensors to telemeter their vital signs to reading stations which may be located at a common passage, such as the entry to a nursing home dining room. Using current sensor technology, body temperature could be read automatically whenever a patient entered the dining room for meals. Similarly heart rate could be telemetered.

3. DESCRIPTION OF THE MICROSTIMULATOR

During the past 7 years, NINDS has funded two contracts to develop subminiature, single channel, telemetry-controlled micro-stimulators and micro-sensors [17-18]. These micro-implants are fully powered by an external magnetic field, contain no active power source, and are small enough to be implanted via a 12-gauge hypodermic needle. It is expected that these devices will provide a step-function in the clinical utility of FES by removing the "hardware barrier", and that significant commercial potential exists for a wide range of subminiature neuroprosthetic and micro- transducers/telemetry devices.

The structure of the first version of the microstimulator is shown in Figure 1 [19]. Overall dimensions of the microstimulators are 1.8 x 1.8 x 9mm. Presently a revised package which uses a different configuration of the components internal to the glass capsulse is at the prototype stage. The NIH-contract allows a package volume of 60 cubic mm for the microstimulator and 125 cubic mm for microimplant sensors.

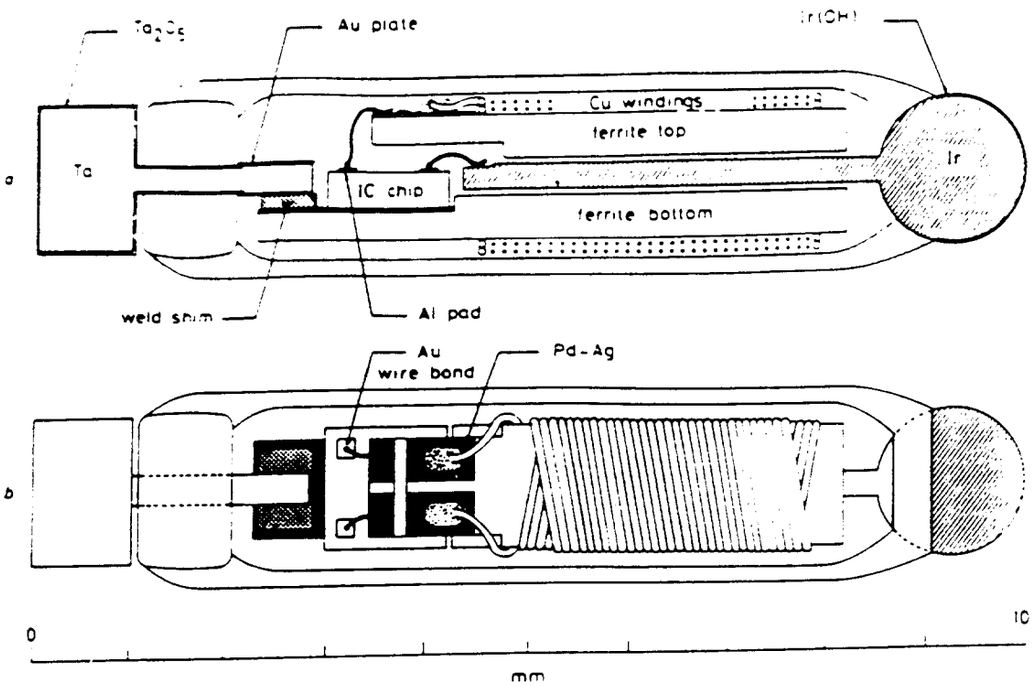

Figure 1. First generation implantable microstimulator (from Loeb et.al. 1991)

3.2 Basic Electrical Operation of the Microstimulator.

An extracorporeal transmitter coil is placed over a region of the body which contains one or more microstimulators. In some cases up to 100 implants might be placed within a specific region, such as a paralyzed limb. For this situation, the transmitter coil might be placed around the limb. The transmitter coil creates a high-intensity magnetic field @ 2MHz which serves to power the passive implant. Modulation of this field by varying the transmitter-coil current allows digital communication with the micro-implants. Each implant is preprogrammed with its own address so that many implants may be individually controlled by a single transmitter coil.

The ferrite-core coil contained within the micro-stimulator has dual functions. First, the coil acts as the secondary winding of a transcutaneous transformer in which the primary coil in the transmitter couples energy into the secondary in order to provide power for the integrated circuit operation. Second, the coil acts to receive digital data modulated on the power carrier for the purpose of implant control (pulse width, amplitude, biphasic recovery current etc). The extreme size difference between the micro-implant and the extracorporeal transmitter means that the magnetic link characteristics are the primary limitation in the system performance.

3.3 Transcutaneous magnetic coupling.

Transcutaneous magnetic inductive coupling has been widely used as a simple method of power and data transfer to implanted devices. The basic scheme is that a receiver coil inside the implanted device is magnetically coupled, via a radio-frequency magnetic field, to an external transmitting coil, thus forming an

air-tissue-core transformer which is capable of transferring both power and data to the implant. Donaldson [20] explains one method by which the same coil inside the implant that is used for power and data transfer into the implanted device can be use to transmit data out. Therefore all power and data transfer can utilize the same magnetic link.

The amount of the magnetic field linked with the implant, relative to the amount of magnetic field produced by the transmitting coil, is called the coefficient of coupling. The coupling coefficient, k, is a measure of the efficiency of the inductive link. Many analyses of transcutaneous inductive links have been presented in the literature [21-24]. Donaldson et al. [23] have shown that for transmitter and receiver coils diameters and relative displacements all on the same order of magnitude, the inductive link can be optimized by finding a "critical value of k". Unfortunately, techniques which are useful to optimize inductive links for systems with comparably-sized transmitter and receiver coils provide little benefit for systems in which the implant's coil is orders of magnitude smaller than that of the external transmitter.

Heetderks [25] has analyzed transcutaneous inductive links which used sub-millimeter sized solenoidal receiver coils. His results indicate that for coils with diameters and relative displacement that are not all on the same order of magnitude, the coefficient of coupling is extremely small and the reflected receiver impedance is negligible. For the microstimulator, we have measured the coefficient of coupling to be on the order of k=0.05.

4 BIDIRECTIONAL TELEMETRY

The microstimulator permits unidirectional communication, forward telemetry, for the purpose of implant control. For a family of micromodules which supports a broader range of functions, bidirectional telemetry is needed. In particular, for implanted sensors the telemetry link will need to support data transfer, reverse telemetry, from the implant to the extracorporeal transmitter. The transmitter/receiver circuitry will also need to accomodate detection of the weaker implant reverse telemetry signal as well as provide modulation of its power carrier for the forward telemetry.

Detection of the reverse telemetry signal is inherently problematic. For the commercially availabe implantable identification transponders, the power carrier, produced by the transmitter, is typically one billion times greater in magnitude than the reverse telemetry signal. This requires that some means of differentiation between the two be incorporated into the transmitter/receiver circuitry.

4.2 Approaches to reverse microtelemetry

There are two basic systems used for reverse telemetry from microimplants: full duplex and half duplex. In the full duplex system, the reverse telemetry signal is placed on a data subcarrier that is an integer submultiple of the power carrier and is transmitted back to the extracorporeal receiver while the power carrier is present. That is, no significant energy is stored in the microimplant so that the transmitter must continue to power the implant during the period of reverse telemetry. As such, the receiver must have a means to reject the relatively large transmitter signal from the relatively weak reverse telemetry signal. This approach is depicted in Figure 2, below.

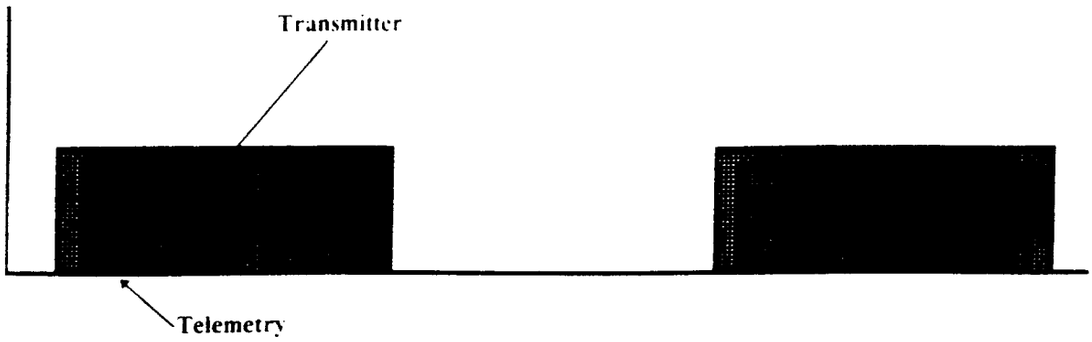

Figure 2. Full duplex approach to microtelemetry

In the half duplex system, the power carrier is used to store energy within the microimplant. Once a sufficient level of energy storage has been achieved, the transmitter is turned off. The cessation of the transmitter is used to trigger the microimplant to begin its reverse telemetry. A local oscillator is keyed by the telemetry data. The stored energy within the microimplant is used to power the implant's circuitry during the telemetry period. This approach is depicted in Figure 3, below.

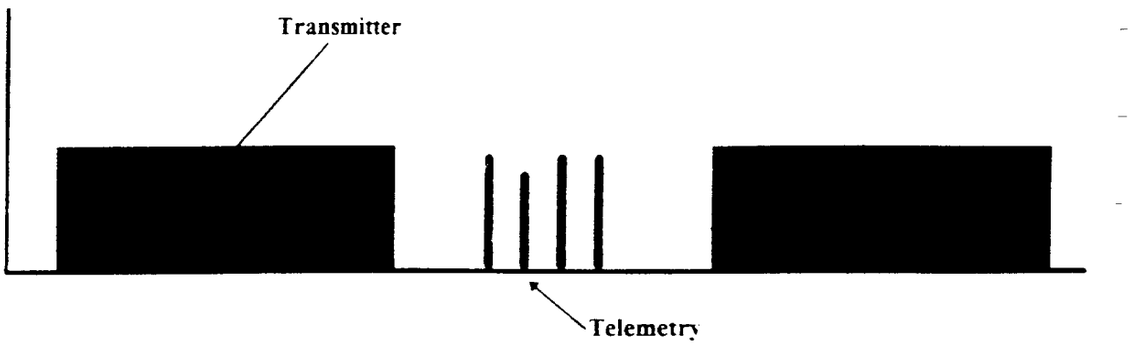

Figure 3. Half duplex approach to microtelemetry

4.3 Full duplex system features

The advantage of full duplex system stems from its simplicity within the microimplant. The data subcarrier is conveniently generated by integer division of the clock derived from the transmitter power carrier. The subcarrier current in the implant's coil is easily generated by synchronous loading of the implant coil. Since no energy storage within the implant is required, the number of discrete components within the microimplant is minimized. There are two primary disadvantages of the full duplex system. First, the presence of the power carrier may interfere with the function of certain implants, such as bioelectric sensors, during the data collection period. Second, the transmitter/receiver must contain either complex rejection circuitry or canceling magnetic assemblies to remove the power carrier from the input to the receiver, or else the reverse telemetry signal is hopelessly obscured.

4 4 Half duplex system features

The advantage of the half duplex system is that the power carrier is turned off during those time periods in which either data is collected, or reverse telemetry is sent This eliminates any possible interference at the biosensor, and significantly simplifies the transmitter receiver circuitry Choosing the data carrier to be at the same frequency as the power carrier permits the optimization of the magnetic link at a single frequency The disadvantages of the half duplex approach are First, depending upon the size of the capacitor, the need for the energy storage capacitor may preclude miniaturization. Second, the integrated circuit design is more complex since a local oscillator, within the implant, must be used to generate the data carrier This oscillator must be combined with the rectification circuitry in the front-end of the implant's integrated circuit.

5 CURRENT MICROIMPLANT DEVELOPMENT

At the present time we are developing a modular approach to bi-directional microtelemetry implants We have chosen a half duplex approach at a frequency of 470kHz. Circuit designs and implant fabrication techniques are being approached with the intention to adapt them to a variety of stimulator/sensor devices We have defined four basic circuit module types: Transceiver, Digital processor, Analog processor, I/O. In this paper we describe the basic operation of the Transceiver. The transceiver module serves the functions of: interface with the implant coil, power supply generation and management, clock recovery, reverse telemetry data carrier generation, and forward telemetry data recovery.

5.2 Implant coil interface

The interface with the implant coil must accommodate the full voltage range produced by the implant coil. Since the spacing between the implant and the transmitter may vary, the implant coil output voltage presented to the implant integrated circuit may range from subthreshold to chip breakdown. For the half duplex system, it is desirable and necessary to allow for a nominal power supply capacitor voltage that is well in excess of the minimum chip operating voltage. This is because the reverse telemetry process discharges the capacitor during telemetry when the transmitter is off. The maximum telemetry time is determined by the time that is takes to discharge the power supply capacitor from its nominal voltage to the minimum chip operating voltage. For typical CMOS, the minimum operating voltage might be approximately 5 volts, and the coil interface circuitry would need to accommodate up to 10-12 volts so that an adequate discharge time is possible. For this reason it is necessary to use high-voltage CMOS processes such as 5-micron. For the remainder of the circuitry, low current drain is desirable and this suggests smaller geometries such as 1.5-micron. Thus, either a dual geometry process, a BI-CMOS process, or multiple chips are required.

5.3 Power supply management

Power supply management must focus upon efficiency due to the limited coupling between the microimplant and the extracorporeal transmitter. We have found it desirable to temporally segment the operation of the implant integrated circuit. Portions of the integrated circuit can be placed in "sleep" mode when not required. For example, when collecting EMG data, one might not operate the digital address decoder, or when preparing for a period of reverse telemetry, all functions expect power supply capacitor charging could be suspended. In this way the power required at the transmitter is kept at a minimum.

5.4 Clock recovery

Clock recovery requires a high-voltage circuit which changes the sinusoidal implant coil voltage to a square-wave clock. Due to the shape of the sinusoid, the CMOS circuitry operates in the linear region for a significant portion of each clock cycle, thus consuming excessive power. We use a schmidt-trigger type of inverter to produce a clock with sharp edges.

5.5 Data carrier generation

Data carrier generation requires the use of a local oscillator. Our approach is to use two cross-wired CMOS transconductance amplifiers in a self-oscillating circuit. The implant coil resonant frequency determines the frequency of the local oscillator. The oscillator is gated on only during periods of reverse telemetry. Modulation of the local oscillator is accomplished using synchronous discharge of the implant coil resonant circuit as shown in Figure 4, below.

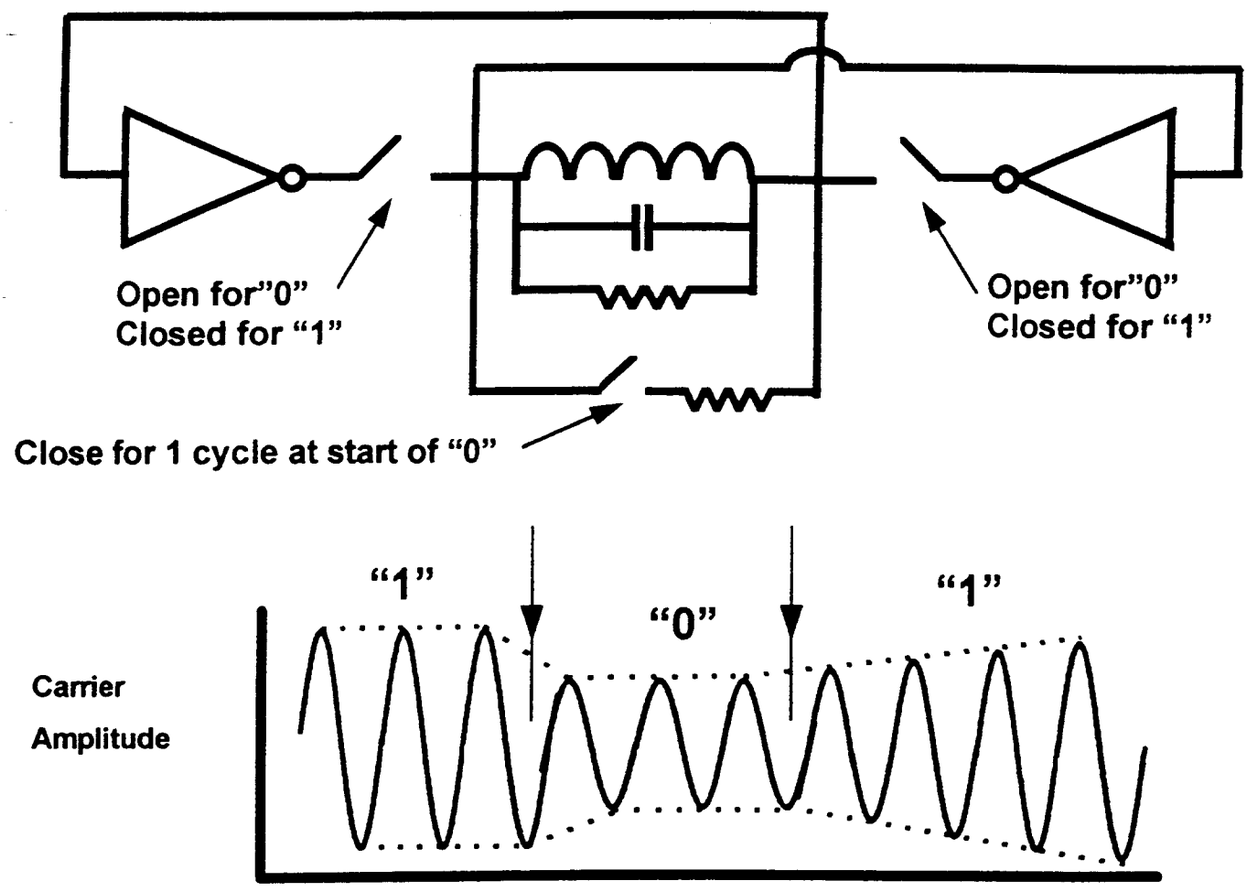

Figure 4. Method of Reverse Telemetry Data Modulation

A transmission of a "1" is accomplished by operation of the local oscillator. Changing from a "1" to a "0" is accomplished by disabling the local oscillator and closing a switch that connects a load resistor across the resonant coil for one cycle. Although the local oscillator is disabled at the onset of a "0", sufficient energy is stored in the resonant circuit so that the coil current "free wheels" for a period of time well in excess of a bit period. Therefore, the momentary loading of the coil reduces the energy content of the resonant circuit, thus changing the amplitude of the coil current. When changing back to a "1", the local oscillator is once again enabled and the coil current rises back to the higher level. This produces an amplitude modulation in the implant coil which matches the digital data.

5.6 Forward telemetry data recovery

Forward data telemetry is produced by the transmitter to command and control the microimplant. These commands may change the state, or function of the addressed device. For example, the mode of, or start of, data collection by the implant sensor could be controlled by the transmitter. Similarly, the command to begin reverse telemetry is provided by the forward data telemetry pathway.

It is desirable to maximize the speed of communication with the implanted devices. A high bandwidth forward telemetry path is in direct conflict with the need to use a high-Q resonant implant coil to maximize power transfer from the transmitter to the implant. Even if the transmitter is turned on and off to produce 100% amplitude modulation, the high-Q of the implant coil will not permit a large change in the coil voltage to occur. However, the energy within the implant coil, under conditions of no transmitter operation, will quickly drop to a level which is below that necessary to continue charging the implants power supply capacitor. Therefore the implant rectifier currents can be used to detect the amplitude modulation of the transmitter. We use a current detector on the lower half of the full-wave rectification circuit, within the implant circuitry, to quickly detect when the transmitter has been turned off. In this manner, we can sense on-off and off-on transitions of the transmitter within 1-2 transmitter carrier cycles. Using voltage amplitude detection would require approximately 8 transmitter cycles to detect a state change.

6. SUMMARY

Microtelemetry technology promises to provide solutions to a wide range of microsensor interface problems. In future work, we anticipate that the implant coil will be integrated directly with the sensor integrated circuit in a secondary wafer-scale operation, thus producing low-cost untethered sensors.

7. ACKNOWLEDGMENTS

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8. REFERENCES

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